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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/751,658	12/31/2000	Rolf C. Anderson	1087.3A-1.1(37US4)	8815

7590

07/23/2002

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EXAMINER

BEISNER, WILLIAM H

ART UNIT

PAPER NUMBER

1744

DATE MAILED: 07/23/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/751,658

Applicant(s)

ANDERSON ET AL.

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 May 2002.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 90-131 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 90-131 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Priority

1. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must be copending with the prior application or with an application similarly entitled to the benefit of the filing date of the prior application.

The instant application is not or was not copending with application 09/210,027 which was filed 12/11/98 and issued on 3/28/00. The instant application was filed on 12/31/00 so it cannot be copending with 09/210,027.

Note the Examiner recognizes Applicants' intention to correct the reference to related applications by changing "This application is also a continuation-in-part" to --U.S. 6,197,595 is also a continuation-in-part--.

Information Disclosure Statement

2. The information disclosure statement filed 18 Oct. 2001 has been considered and made of record.

Claim Objections

3. Claim 97 is objected to because of the following informalities: Claim 97 depends from itself. It appears that the claim should depend from claim 96 and will be examined as though it depends from this claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 127-131 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 127-131 are indefinite because it is not clear how the language of these claims further limits the structure of the device of claim 117. These claims appear to be further limiting method steps which are intended to be performed in the device.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 90, 92-94, 96 and 117 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown (US 4,676,274).

The reference of Brown discloses a device and method of use which includes a microfabricated device (See Fig. 13 and 14) which includes a volumetric chamber with a vent port and a second chamber (119) with a vent port. The chambers are provided in communication

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with a reduced diameter channel (118). As shown in Figure 1, the system includes external valves and pumps and compressors for controlling the flow of fluid through the volumetric chamber.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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11. Claims 91, 98 and 99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown (US 4,676,274).

The reference of Brown has been discussed above.

With respect to claim 91, while the reference discloses the use of channels (See column 9, lines 22-44), the reference is silent as to the specific dimensions of the channels. However, based merely on the properties of the fluids which are to be manipulated by the device and/or the specifics of the procedure to be performed, it would have been obvious to one of ordinary skill in the art to optimize the dimensions of the channels.

With respect to the use of a negative pressure rather than a positive pressure, the use of a vacuum in place of a positive pressure would have been merely an obvious matter in design choice since both are known in the art for effecting the flow of fluid upon acting on the fluid.

12. Claim 95 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brown (US 4,676,274) in view of Bochner (US 5,589,350).

The reference of Brown has been discussed above.

Claim 95 differs by reciting the use of a hydrophobic membrane positioned over a vent port.

The reference of Bochner discloses that the use of hydrophobic membranes (750) over vent ports is known for allow gas to escape while containing a liquid sample (See Figures 13-15).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ a hydrophobic membrane over the vent port of the device of Brown for the known and expected result of preventing the escape of liquid from the device during use.

13. Claims 101-116 and 118-131 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown (US 4,676,274) in view of Wilding et al.(US 5,498,392).

The reference of Brown has been discussed above.

The above claims differ by reciting the use of structure and method steps specific for nucleic acid processing.

The reference of Wilding et al. discloses a microfluidic system which is known in the art for controlling a nucleic acid reaction and detection. The system includes a plurality of chambers and the use of vent ports and pumps for the manipulation of a fluid sample within the device.

In view of this teaching, it would have been obvious to one of ordinary skill in the art to perform the nucleic acid manipulations disclosed by the reference of Wilding et al. using a sample manipulation system which functions as disclosed by the reference of Brown for the known and expected result of providing an alternative means recognized in the art to achieve the same result, control of the movement of a fluid sample within a microfluidic device. Note Figure 18 of Brown which discloses a microfluidic system which employs the fluid control taught by the reference of Brown.

Double Patenting

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14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 90-131 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,197,595. Although the conflicting claims are not identical, they are not patentably distinct from each other because The instant claims are anticipated by the claim of the patent because the instant claims do not preclude the use of a common channel for the application of the external pressure. With respect to the specifics of the nucleic acid features of the device, the use of microfluidic devices to perform nucleic acid reactions is known in the art and would have been obvious to provide the device of the patented claims with the additional control and detection zones.

Response to Arguments

16. Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

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17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 703-308-4006. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:40am to 4:10pm.

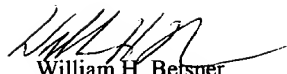
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Warden can be reached on 703-308-2920. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

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William H. Belsner
Primary Examiner
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WHB

July 15, 2002